

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Claims 1-45 are pending. Claims 5, 6, 8, 15-22 and 24-45 stand withdrawn. Claims 1, 2, 4, 7, 12 and 13 are amended herein. New claims 46-49 are added. Basis for the amendments and new claims may be found throughout the specification as-filed, especially in the claims as filed. Claims 3, 5-6, 8-11, 15-22 and 24-45 are canceled herein. No new matter is introduced by way of the present Amendment. Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled by way of the present Amendment.

Objections to the Claims

Claims 1-4 and 7 are objected to for purportedly encompassing non-elected embodiments. Independent claim 1 is amended herein to incorporate the subject matter of claims 9 and 10, thus reciting elected subject matter.

Claim 23 is objected to as purportedly dependent upon a non-elected claim (claim 8). Claim 23 is amended herein to depend on claim 7. Thus, this rejection is obviated.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-4, 7, 9-14, and 23 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement.

Specifically, the Office Action states that the rejected claims are directed to method of introducing a substance comprising a nucleic acid into mammalian neuronal stem or progenitor cells, but that the specification merely demonstrates that the rat neuronal stem or progenitor cells are competent for DNA transfection without the need for treatments commonly required for transfection of mammalian cells.

Applicants respectfully traverse.

With regard to the written description requirement, Applicants submit that the Examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). *See also* M.P.E.P. § 2163.

There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *Id.*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis. *See In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). To this end, the subject matter of the claim need not be described literally (*i.e in haec verba*) in order for the disclosure to satisfy the description requirement.

Applicants submit that the Examiner has not met the burden in showing that the skilled artisan cannot extrapolate from rat progenitor cells to other mammalian

stem/ progenitor cells. Nor has the Examiner met the burden of showing that there is any reason to doubt what is disclosed in the application.

The Office Action further states that the concept of how a nucleic acid "directly interacts" with the cell membrane or component is not clearly explained in the specification. As amended claim 1 no longer recites "directly interacts".

In light of the above remarks and amendments, Applicants request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-4, 7-14, and 23 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite.

Claim 1 stands rejected for the recitation of "...wherein said nucleic acid directly interacts with the cell membrane of said cell or a component within said cell membrane *in vitro* whereby the substance comprising said nucleic acid is taken up by the cell via the inherent transport mechanism of the cell...", as this phrase is purportedly unclear. Claim is amended herein to remove these phrases. Thus, this rejection is obviated.

Claim 2 stands rejected, as it is purportedly unclear as to the nature and number of steps required in order to generate a "derivative" of an adult cell. Claim 2 is amended herein to replace "derived from" with "obtained from", as suggested by the Examiner. Thus, this rejection is obviated. Claim 3 stands rejected, as the phrase "humid atmosphere" is purportedly unclear. Claim 3 is deleted herein. Thus, this rejection is moot.

Claim 7 stands rejected as the term "specific cDNA" is purportedly unclear. Claim 7 is amended herein to remove "specific". However, Applicants note that the term "cDNA" is specific in itself, in that the skilled artisan knows what is meant by a cDNA. Specifically, the skilled artisan would recognize that a cDNA is a coding DNA sequence corresponding to a specific sequence of mRNA. Thus, Applicants request that this rejection be withdrawn.

Claims 9-11 stand rejected for the recitation of the phrase "gives rise to", as this phrase is purportedly vague. Claim 1 is amended herein to incorporate claim 9-10, and to remove "give rise to". Thus, this rejection is obviated.

Claim 13 stands rejected. Claim 13, dependent upon claim 11, purportedly recites that the detectable signal is due to a radioactively tagged nucleic acid. Claim 11, however, recites that the peptide or protein encoded by the transfected nucleic acid gives rise to a detectable signal. Claim 13 is amended herein to depend from claim 1 to provide antecedent basis. Thus, this rejection is obviated.

Claim 23 stands rejected for the recitation that the detectable signal allows for testing or an expressed protein or signal comprised within or encoded by the transfected nucleic acid. Claim 23 is amended herein to recite "used for" testing and screening to clarify the claimed subject matter.

Applicants request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1, 7, 9-11, 14, and 23 stand rejected under 35 U.S.C. § 102(e) as purportedly anticipated by Anderson *et al.* (U.S. Patent No. 6,001,654). Applicants traverse.

"[A]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention as arranged in the claims." *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). Anderson fails to describe or even suggest all of the elements of the rejected claims.

Claim 1, as amended herein, recites a method for introducing a substance comprising a nucleic acid into a mammalian neural stem cell or progenitor cell, *in vitro*, wherein the substance gives a detectable signal or encodes a peptide or protein that enables selective identification of the cells, the method comprising (i) bringing the substance into contact with the cell, wherein step (i) is the only prerequisite for the uptake of the substance by the cell. Thus, the claims of the present invention are directed to a method that selectively introduces nucleic acids that can be used as markers into neural stem cells, without the aid of any other chemical compounds or viral infection.

Anderson discloses various methods of transforming mammalian cells, known in the art, such as DEAE-mediated transfer, calcium-phosphate-mediated precipitation, microinjection, lipofection and viral infection. Thus, Anderson discloses methods of transformation that require other chemical compounds and/or viral intervention. Thus, Anderson not only fails to recite the elements of the present claims, but also teaches away from the claimed invention.

As Anderson does not recite the elements of the claimed invention, Applicants request that this rejection be withdrawn.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited. In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney so that prosecution of this application may be expedited.

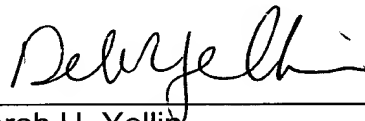
In the event any further fees are due to maintain pendency of this application, the Examiner is authorized to charge such fees to Deposit Account No. 02-4800.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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By:



Deborah H. Yellin
Registration No. 45,904

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620